UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LIGIA VANESSA CHAPETON, an individual, and GARY SEYMOUR, an individual, Plaintiffs, v. MEDTRONIC, INC., a Minnesota corporation; MEDTRONIC SOFAMOR DANEK, USA, INC., a Tennessee corporation; ROGER HARTL, M.D., an individual, Defendants.	Case No. 1:14-CV-00866-JGK

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Plaintiffs Ligia Vanessa Chapeton ("Mrs. Chapeton") and Gary Seymour (collectively "Plaintiffs") move the Court to remand this case to the Supreme Court of the State of New York, County of New York for lack of subject-matter jurisdiction. In support, Plaintiffs state as follows:

I. INTRODUCTION

A. Factual Background

On June 9, 2011, Mrs. Chapeton underwent spine surgery. Compl. ¶ 343. Defendant Dr. Roger Hartl ("Dr. Hartl") fused Mrs. Chapeton's vertebrae at the L5-SI levels using Infuse®, a bio-engineered liquid bone protein (the Infuse® Bone Protein) produced and manufactured by Defendants Medtronic, Inc. and its subsidiary Medtronic Sofamor Danek, USA, Inc. (collectively "Defendants"). The Infuse® Bone Protein and a specific hollow metal cylinder called an LT-CAGE™ together comprise the Infuse® Combination Device. The Food and Drug Administration ("FDA") has not approved any use of the Infuse® Bone Protein without the requisite LT-CAGE™ and has only approved the Combination Device for cervical spinal fusions performed from the front of the body (anterior approach). *Id.* at ¶ 2. The use of the Infuse® Bone Protein in Mrs. Chapeton's surgery was unapproved by the FDA and "off-label" because Dr. Hartl (1) did not use the requisite LT-CAGE™, and (2) implanted the Bone Protein from the back (posterior approach). *Id.* at ¶ 343.

Neither Dr. Hartl nor Medtronic warned Mrs. Chapeton that this use of the Infuse® Bone Protein was off-label and could cause her vertebrae to grow uncontrollably, thereby impinging on her spinal cord and causing chronic pain, paralysis, or even death. *Id.* at ¶ 344. Unfortunately, this is exactly what happened. Mrs. Chapeton developed uncontrolled bone growth which led to severe nerve damage, osteolysis, stenosis, and cystic changes at or near the site of her fusion. *Id.* at ¶ 345. Mrs. Chapeton was forced to undergo a revision surgery to

remove the bone overgrowth and to re-do the failed fusion. *Id.* at ¶ 346. But the damage was done, and Mrs. Chapeton continues to suffer from severe injuries including chronic pain in her legs, feet, and toes. *Id.* at ¶ 347.

Based on this series of events and on Medtronic's decade-long scheme of fraudulently promoting the off-label use of Infuse® and concealing known risks associated with it, Plaintiffs asserted a number of traditional state-law causes of action against Defendants in the Supreme Court of New York, County of New York. Medtronic improperly removed the action to this Court, erroneously arguing that issues raised by their claimed defense of federal preemption establish federal question subject-matter jurisdiction.[1]

B. Preemption Landscape

The Infuse® Bone Protein has not itself been subjected to FDA review. In contrast, the Infuse® Combination Device is a Class III medical device subject to the approval and conditions of the Federal Food Drug and Cosmetic Act ("FDCA") and the Medical Device Amendment Act ("MDA"). Those laws include a limited preemption provision which the United States Supreme Court has interpreted in a trilogy of landmark cases: *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); and *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008).

This precedent provides that traditional state law causes of action escape preemption if they impose no requirements greater than or in addition to federal requirements, but would survive even in the absence of those federal requirements. *Lohr*, 518 U.S. at 495; *Riegel*, 552 U.S. at 330; *Buckman*, 531 U.S. at 353. In other words, to defeat a defense of federal

[1] Medtronic does not argue that Plaintiffs fraudulently joined Dr. Hartl or, therefore, that the Court may assert jurisdiction based on diversity of the parties. Because the burden of proving jurisdiction lies with the removing party, *Farace v. Pereira*, No. 04 Civ. 1880 (RWS), 2004 U.S. Dist. LEXIS 13902, *5 (S.D.N.Y. July 22, 2004) (Koeltl, J.) (citations omitted), Plaintiffs do not address the propriety of their claims against Dr. Hartl.

preemption, plaintiffs must be suing for conduct that violates a federal law or regulation, but that would constitute an independent violation of the asserted state law theories even if those federal requirements did not exist. *Lohr*, 518 U.S. at 495; *Riegel*, 552 U.S. at 330; *Buckman*, 531 U.S. at 353. These "parallel claims" are exactly the kind that Plaintiffs assert here.

C. Summary of the Argument

Plaintiffs have pleaded only state law causes of action. Plaintiffs' anticipatory reference to federal regulations does not transform the nature of their claims, and Medtronic cannot create a federal question by asserting a defense rooted in federal preemption. This conclusion finds support in the overwhelming weight of binding precedent and in the great majority of decisions of district courts across the country addressing this issue in the context of lawsuits arising from injuries due to the off-label use of Infuse® in spinal fusion surgery. Plaintiffs are aware of six district court decisions addressing whether the allegations relating to Medtronic's off-label promotion of Infuse® established federal-question jurisdiction. Four of them found it did not. *See Mooney v. Henkin*, No. 8:13-cv-3213-T-26AEP, 2014 U.S. Dist. LEXIS 16432 (M.D. Fla. Feb. 9, 2014); *Dillon v. Medtronic, Inc.*, No. 13-105-ART, 2014 U.S. Dist. LEXIS 747 (E.D. Ky. Jan. 6, 2014); *Goade v. Medtronic, Inc.*, No. 13-5123-CV-SW-ODS, 2013 U.S. Dist. LEXIS 169961 (W.D. Mo. Dec. 2, 2013); *David v. Medtronic, Inc.*, No. 13-cv-0441 DMG CW, (C.D. Cal. Aug. 6, 2013).[2] Medtronic's arguments to the contrary are disingenuous and dilatory. Accordingly, this Court lacks subject-matter jurisdiction and should remand the case to state court and award Plaintiffs all of their costs and fees associated with the improper removal and the instant Motion.

[2] Two decisions have come out the other way. *See H.R. v. Medtronic, Inc.*, No. 1:13-cv-859, 2014 U.S. Dist. LEXIS 18419 (S.D. Ohio Feb. 13, 2014); *Jenkins v. Medtronic, Inc.*, No. 2:13-cv-02004-JTF-cgc, 2013 U.S. Dist. LEXIS 165787 (W.D. Tenn. Nov. 21, 2013).

II. LEGAL STANDARD

"Federal courts are courts of limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of America*, 511 U.S. 375, 377 (1994). A district court may properly entertain a removed action only if it has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 or 1332. "The burden is on the removing party to prove that it has met the requirements for removal." *Farace*, 2004 U.S. Dist. LEXIS 13902, at *5 (Koeltl, J.) (citations omitted). Removal jurisdiction must be strictly construed. *Id.*

III. ARGUMENT

A. The Court Lacks Subject-Matter Jurisdiction and Must Remand the Case.

Courts may exercise federal-question jurisdiction over a removed case only if (1) "federal law creates the cause of action asserted" or (2) the asserted claims raise a "substantial" federal issue "capable of being resolved without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 133 S. Ct. 1059, 1064–65 (2013). Neither avenue is open here.

1. Plaintiff's Well-Pleaded Complaint Invokes Only State Law Claims and Does Not Give Rise to Federal-Question Jurisdiction.

It is well settled that a plaintiff is the masters of his own complaint. *Holmes Group, Inc. v. Vornado Air Circulation Sys.*, 535 U.S. 826, 831 (2002). Accordingly, under the well-pleaded complaint doctrine, "federal-question jurisdiction exists only if a plaintiff's statement of his own cause of action shows that it is based on federal law." *Calabro v. Aniqa Halal Live Poultry Corp.*, 650 F.3d 163, 166 (2d Cir. 2011) (citations omitted); *accord Cuomo v. Dreamland Amusements, Inc.*, No. 08 Civ. 7100 (JGK), 08 Civ. 6321 (JGK), 2008 U.S. Dist. LEXIS 71432, *9 (S.D.N.Y. Sept. 22, 2008) (Koeltl, J.) ("[R]emoval based on federal-question jurisdiction is improper unless a federal claim appears on the face of the well-pleaded complaint.") (quotations omitted).

Here, Plaintiffs plead only state-law claims, including negligence, fraud, strict products liability, and breach of warranty. Anticipating the defense of federal preemption, which Medtronic has asserted in dozens of Infuse®-related cases, Plaintiffs also reference federal regulations. They do so to show that state and federal requirements run parallel, *not*, as Medtronic suggests, as an independent basis for a federal action. Assertions in the complaint that are not necessary to establish affirmative elements of a claim are irrelevant for the purpose of assessing federal-question jurisdiction under the well-pleaded complaint rule. *Vaden v. Discover Bank*, 556 U.S. 49, 50 (2009); *Louisville & Nashville R.R. Co. v. Mottley*, 211 U.S. 149, 152 (1908). Thus, Plaintiffs' reference to federal requirements which parallel state law has no effect on the essential nature of their claims and does not create federal jurisdiction.

Similarly, "it is well established that a defendant may not evade" the well-pleaded complaint doctrine "by raising federal question in its responsive pleadings and then attempting to remove on that basis." *Calabro*, 650 F.3d at 166 (citations omitted). The Supreme Court has observed that "since 1887 it has been settled law that a case may not be removed to federal court on the basis of a federal defense, including the defense of pre-emption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties admit that the defense is the only question truly at issue in the case." *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 14 (1983), *superseded by statute on other grounds*, 28 U.S.C. § 1441(e); *accord Box Tree S. v. Bitterman*, 873 F. Supp. 833, 837 (S.D.N.Y. 1995) (Koeltl, J.) (quoting *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 398 (1987)) ("[T]he fact that a defendant might ultimately prove that a plaintiff's claims are pre-empted under [a federal statute] does not establish that they are removable to federal court."). Pursuant to clear, binding precedent, therefore, Medtronic's

defense of federal preemption does not transform Plaintiffs' state law claims into federal ones and does not create a basis for this Court to assert jurisdiction over them.

Finally, Medtronic cannot be heard to argue that the FDCA completely preempts state tort law—no court has reached that conclusion, and the statute expressly preserves traditional state law actions that parallel the requirements under the federal regime. *See Lohr*, 518 U.S. at 495; *Riegel*, 552 U.S. at 330 (The FDCA "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."). The doctrine of complete preemption applies in very limited circumstances. *See Bill Johnson's Restaurants, Inc. v. N.L.R.B.*, 461 U.S. 731, 752 (1983). Indeed, the Supreme Court has found only three statutes to have such effect, and the Second Circuit has added only one. *See Cuomo*, 2008 U.S. Dist. LEXIS 71432, at *15 (Koeltl, J.). "Expansion of existing categories is discouraged." *Id.* More importantly, courts specifically assessing the FDCA have determined that it does not so completely preempt state law as to create an independent basis for federal jurisdiction. *See Dillon*, 2014 U.S. Dist. LEXIS 747, at *23 (citing *Strong v. Telectronics Pacing Sys., Inc.*, 78 F.3d 256, 259–61 (6th Cir. 1996)). Such a conclusion would undermine Congress' clear intent to preserve certain traditional state-law actions. *See Lohr*, 518 U.S. at 495; *Riegel*, 552 U.S. at 330.

2. <u>The Complaint Raises No Substantial Federal Question.</u>

Plaintiffs' Complaint does not raise a "substantial" federal question sufficient to establish federal jurisdiction over claims arising under state law. "Federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of being resolved without disrupting the federal-state balance approved by Congress." *Gunn*, 133 S. Ct. at 1065. Plaintiffs' claims do not *necessarily* raise a federal issue,

and any federal question implicated by Medtronic's defense is insufficiently substantial to confer federal jurisdiction.

There is no affirmative federal "element" to any of Plaintiffs' traditional state law claims. Medtronic argues Plaintiffs "cannot state a claim and cannot prevail without demonstrating a violation of relevant federal requirements." Notice ¶ 22. This is incorrect. A defendant asserting that federal law preempts a state law claim bears the burden of showing that federal preemption applies. Only then, in order to rebut a *defense* based on federal preemption, Plaintiffs must demonstrate that the conduct giving rise to their state law claims also violates federal requirements. But, in accord with the well-settled principle that defenses do not confer federal jurisdiction, a federal issue is not necessarily *raised* if it derives only from the defense. *See David*, No. 13-cv-0441, slip op. at *5 (citing *Grable & Sons Metal Prods. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005)) ("The fact that Plaintiffs may need to establish a parallel federal requirement to avoid preemption of some or all of their claims is part of Defendants' preemption defense," and therefore "[i]nterpretation of the FDCA is not an 'essential element' of Plaintiff's claims . . . ."); *Dillon*, 2014 U.S. Dist. LEXIS 747, at *20 ("[E]ven if a federal question in this case is substantial, it must appear on the face of the Dillons' well-pleaded complaint. Put differently, a federal issue must be among the allegations necessary for the Dillons to plead their state causes of action, Other federal issues governing whether their claims ultimately entitle them to relief are irrelevant.").

Three Supreme Court cases further demonstrate that no substantial federal issue justifies asserting federal jurisdiction over Plaintiffs' inherently state-law claims. In *Merrell Dow*, the Supreme Court assessed the FDCA, the very statute that is the basis of Medtronic's preemption defense, and concluded that because the statute lacked a private right of action, the federal issues

raised as an element of the state cause of action were insufficiently substantial to transform the action into a federal one. *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 817 (1986). Because Congress did not include a private right of action, the Court reasoned, it "did not intend a private federal remedy for violations of the statute it enacted." *Id.* at 811. It would therefore "flout congressional intent" to allow federal courts to "exercise federal-question jurisdiction and provide remedies for violations of that federal statute solely because the violation of the federal statute" was an element of the state claim. *Id.* at 812. Thus, the absence of a federal cause of action is a significant factor in determining whether a federal issue gives rise to federal jurisdiction. *See Grable*, 545 U.S. at 317–19; *Goade*, 2013 U.S. Dist. LEXIS 169961, at *8.

In *Merrell Dow* the Supreme Court "explicitly held that a state tort claim incorporating allegations that the FDCA has been violated does not arise under federal law for purposes of section 1331." *See Goade*, 2013 U.S. Dist. LEXIS 169961, at *8. Medtronic's attempts to distinguish *Merrell Dow* are unavailing; the case remains good law generally and for the "specific holding with respect to state claims incorporating elements of the FDCA." *Id.*

Finally, the Supreme Court's decisions in *Grable* and *Gunn* demonstrate that substantiality is judged not by the effect on the parties but by "some importance external to the suit at hand." *Id.* (citing *Grable*, 545 U.S. at 319–20; *Gunn*, 133 S. Ct. at 1066). In *Grable* the federal issue was substantial because it implicated a central concern of the federal government: the ability of a federal agency (the IRS) to collect taxes and the compatibility of that agency's regulations with other federal laws. In contrast, the underlying federal issue in *Gunn* was merely the construction of federal patent law, and was not deemed to confer federal jurisdiction. 133 S. Ct. at 1066–67.

The only federal "issue" in this case, like that in *Gunn*, concerns the parties to this litigation and does not implicate an interest of substantial federal concern. There is no constitutional question at stake. Nor do Plaintiffs challenge the validity of any federal law, including the FDCA or its preemption clause. It is beyond dispute that the FDCA preserves parallel traditional state law claims. *See Riegel*, 552 U.S. at 330. The federal issue raised by Medtronic's *defense* is simply whether Plaintiffs' claims are among those that escape preemption. This issue is not of such great "importance . . . to the federal system as a whole" to justify rewiring the nature of Plaintiffs' claims. *See Gunn*, 133 S. Ct. at 1066. Such a finding would relegate Plaintiffs from masters of their complaint to slaves of a defense.

B. Medtronic's Improper Removal Lacked an Objectively Reasonable Basis and Justifies Awarding Plaintiffs Their Associated Costs and Fees.

The great weight of legal authority makes clear that Plaintiffs' claims do not confer federal jurisdiction. In fact, the Supreme Court has already determined that federal issues implicating the FDCA that are raised as an element of a state cause of action are insufficiently substantial to transform the action into a federal one. *Merrell Dow*, 478 U.S. at 817. Moreover, it "is well established that a defendant may not . . . rais[e] a federal question in its responsive pleadings and then attempt[] to remove on that basis." *Calabro*, 650 F.3d at 166. Thus, Medtronic lacked an objectively reasonable basis to remove, and the Court may properly award Plaintiffs' their fees and costs associated with the removal and instant Motion. *See* 28 U.S.C. § 1447(c); *Calabro*, 650 F.3d at 166. Plaintiffs respectfully request that the Court do just that.

Indeed, Medtronic has already been warned not to attempt removal on these grounds. In *Goade*, decided in December 2013, Judge Smith noted that many of the cases relied upon by Medtronic advanced overly permissive interpretations of *Grable* that were of "doubtful validity

in light of *Gunn*." 2013 U.S. Dist. LEXIS 169961, at *21. As such, Medtronic's failure to raise *Gunn* constituted a "disturbing" "lack of candor." [3] Judge Smith thus issued a stern warning:

> The Medtronic Defendants are now on fair notice that if they rely on these arguments **in a future case, a district judge might be justified in concluding they lack an objectively reasonable basis for removal.** This is (as far as the Court can tell) their third failure and the omission of the Supreme Court's latest pronouncement on the issue has been brought to their attention.

Id. (emphasis added).

Medtronic—represented by the same counsel in that action as this one—has blatantly and brazenly ignored this warning. Judge Smith told Medtronic that making the same arguments again, especially without citing or attempting to distinguish *Gunn*, would be dishonest and likely sanctionable. And yet that is exactly what Medtronic has done.

Medtronic's removal not only contravenes well-established precedent, it does so in violation of an express judicial warning. The removal therefore was objectively unreasonable and justifies an award of Plaintiffs' costs and fees associated therewith. Plaintiffs' counsel are prepared to submit affidavits in support of their costs, expenses, and attorney fees incurred as a result of this motion practice.

IV. CONCLUSION

Plaintiffs plead only traditional state law claims. The reference to parallel federal requirements does not convert the claims into federal ones. Moreover, the federal issues implicated by Medtronic's preemption defense do not confer federal-question jurisdiction because they are not (a) essential to Plaintiffs' affirmative claims or (b) sufficiently substantial to justify upsetting the balance between state and federal courts. These principles are well

[3] In fairness, Judge Smith also expressed frustration with plaintiffs' counsel for not explaining that of ten cited cases for a certain proposition, nine had been decided by the same court. *See* 2013 U.S. Dist. LEXIS 169961, at *21.

established. Thus, Plaintiffs respectfully request that the Court remand this case to the Supreme Court of the State of New York, County of New York, and order Medtronic to pay the costs and fees Plaintiffs incurred in opposing Medtronic's objectively unreasonable removal.

Dated: March 12, 2014

Respectfully submitted,

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☐ by mailing a true and correct copy thereof by U.S. Postal Service, ordinary first class mail, addressed to each attorney's last-known address and depositing in the U.S. mail at San Francisco, California, on the date set forth above;

☐ by mailing a true and correct copy thereof by U.S. Postal Service, certified mail, return receipt requested, addressed to each attorney's last-known address and depositing in the U.S. mail at San Francisco, California, on the date set forth above;

☐ by causing a true and correct copy thereof to be hand-delivered to the above-mentioned attorneys at each attorney's last-known office address on the date set forth above;

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